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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,778	08/02/2004	Muhammed Majeed		4777

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/710,778	MAJEED ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/22/07 has been entered.

Claims 11-20 are pending in the application and were examined on their merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59-66 of copending Application No. 11/417,155 in view of Ammon et al. (EP 552657 A1) in view of Balch et al. (1997) in view of Yegorova (US 20020176900 A1).

Claims 59-66 of '155 specifically teach treatment of psoriasis with boswellic acid derivatives such as beta-boswellic acid. The claims of '155 do not specifically teach wherein boswellic acid derivatives are combined with selenium compounds such as selenomethionine to be taken orally, while concurrently applying boswellic acid to the skin for treatment of psoriasis, nor the particular amount of boswellic acid derivatives or selenium compounds.

Ammon et al. (EP 552657 A1) teach that boswellic acid and its derivatives including beta-boswellic acid, 11-keto-beta-boswellic acid, alpha-boswellic acid, acetyl-boswellic acid, acetyl-alpha-boswellic acid and acetyl-11-keto-beta boswellic acid can be used for treating inflammation disorders such as psoriasis (see English Derwent Abstract). Ammon et al. report that the boswellic acid compounds "...selectively influence inflammations [*sic*, inflammation] by inhibiting leukotriene synthesis. They can be used to replace steroidal antirheumatic drugs and can be used for prolonged periods

without causing side effects". Ammon et al. further teach that the boswellic acid derivatives could have been used orally or topically (*inter alia*).

Balch et al. (1997) specifically teaches that selenium is a *very important* nutrient for taking internally when suffering from psoriasis as it "has powerful antioxidant properties" (see pp. 452-454 under 'Psoriasis', especially p. 454 column 1 'Nutrients').

Yegorova (US 20020176900 A1) states that "Selenomethionine is the most bioavailable form of selenium" (see [0052]).

One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because 1) boswellic acid derivatives were known to be used orally and topically for treatment of psoriasis, 2) selenium was known to be taken for treatment of psoriasis and 3) selenomethionine was well-known in the art as being the most bioavailable form of selenium. The ordinary artisan, having the instant references before him, all pertinent to the claimed invention as they are directed toward the same art, would have combined the elements in order to arrive at a predictable result; i.e., treatment of psoriasis.

Although the prior art did not point specifically to the amounts of boswellic acid and selenium compounds as Instantly claimed, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or

workable ranges ***involves only routine skill in the art***. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955) emphasis added. see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature which does not constitute a non-obvious combination.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ammon et al. (EP 552657 A1) English Abstract provided by Derwent in view of Balch et al. (1997) in view of Yegorova (US 20020176900 A1).

Ammon et al. (EP 552657 A1) teach that boswellic acid and its derivatives including beta-boswellic acid, 11-keto-beta-boswellic acid, alpha-boswellic acid, acetyl-

boswellic acid, acetyl-alpha-boswellic acid and acetyl-11-keto-beta boswellic acid can be used for treating inflammation disorders such as psoriasis (see English Derwent Abstract). Ammon et al. report that the boswellic acid compounds "...selectively influence inflammations [*sic*, inflammation] by inhibiting leukotriene synthesis. They can be used to replace steroidal antirheumatic drugs and can be used for prolonged periods without causing side effects". Ammon et al. further teach that the boswellic acid derivatives could have been used orally or topically (*inter alia*).

Ammon et al. did not teach the incorporation of selenium such as selenomethionine for treatment of psoriasis nor the particular dosage amounts of boswellic acid derivatives and selenium compounds.

Balch et al. specifically teaches that selenium is a very important nutrient for taking internally when suffering from psoriasis as it "has powerful antioxidant properties" (see pp. 452-454 under 'Psoriasis', especially p. 454 column 1 'Nutrients').

Yegorova (US 20020176900 A1) states that "Selenomethionine is the most bioavailable form of selenium" (see [0052]).

One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because 1) boswellic acid derivatives were known to be used orally and topically for treatment of psoriasis, 2) selenium was known

to be taken for treatment of psoriasis and 3) selenomethionine was well-known in the art as being the most bioavailable form of selenium. The ordinary artisan, having the instant references before him, all pertinent to the claimed invention as they are directed toward the same art, would have combined the elements in order to arrive at a predictable result; i.e., treatment of psoriasis.

Although the prior art did not point specifically to the amounts of boswellic acid and selenium compounds as Instantly claimed, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges ***involves only routine skill in the art***. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955) emphasis added. see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature which does not constitute a non-obvious combination.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

A translation of Ammon et al. (EP 552657 A1) has been ordered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

July 31, 2007